We Claim

1. An aqueous Ifosfamide composition having reduced toxicity for parenteral administration comprising Ifosfamide and 2-hydroxylpropyl-β-cyclodextrin, wherein the Ifosfamide is present at a concentration up to 1,100 mg/ml.

2. The composition of claim 1, wherein the Ifosfamide is present at 1-200 mg/ml.

3. The composition of claim 1, wherein the Ifosfamide is present at 10-100 mg/ml.

4. The composition of claim 1, wherein the Ifosfamide is present at 40-50 mg/ml.

5. The composition of claim 1, wherein the Ifosfamide is present at 200-500 mg/ml.

6. The composition of claim 1, wherein the Ifosfamide is present at 500-1,000 mg/ml.

7. The composition of claim 1, wherein the concentration of Ifosfamide is greater than 1,000 mg/ml.

8. The composition of claim 1, wherein the 2-hydroxypropyl-β-cyclodextrin has a molar substitution by hydroxy propyl groups of 0.05 - 2.

9. The composition of claim 1, wherein the 2-hydroxypropyl-β-cyclodextrin has a molar substitution by hydroxy propyl groups of 0.3 - 1.5.

10. The composition of claim 1, wherein the 2-hydroxypropyl-β-cyclodextrin has a molar substitution by hydroxy propyl groups of 0.5 - 1.2.

11. The composition of claim 1 wherein the molar ratio of Ifosfamide to 2-hydroxypropyl-β-cyclodextrin is 100:0.1 - 1:300.

12. The composition of claim 1, wherein the molar ratio of Ifosfamide to 2-hydroxypropyl-β-cyclodextrin is 100:0.25 - 1: 100

13. The composition of claim 1, wherein the molar ratio of Ifosfamide to 2-hydroxypropyl-β-cyclodextrin is 100:1 - 1: 20

14. The composition of claim 1, wherein the molar ratio of Ifosfamide to 2-hydroxypropyl-β-cyclodextrin is 100:3.3 - 1:2.5.

15. The composition of claim 1, further comprising pharmaceutically acceptable buffers, tonicity agents, preservatives, chelating agents, antioxidants, or anti-crystallizing agents.

16. The composition of claim 15, wherein the pH of the composition is between 3.0 -9.0.

17. The composition of claim 16, wherein the pH of the composition is between 5.0 - 8.0.

18. The composition of claim 15, wherein the buffering agent is selected from the group consisting of Sodium dihydrogen phosphate, Disodium hydrogen phosphate. Dipotassium hydrogen phosphate, Potassium dihydrogen phosphate, Histidine HCl, Sodium Hydroxide, Phosphoric acid, and Hydrochloric acid and mixtures thereof.

19. The composition of claim 18, wherein the buffering agent is a mixture of Sodium dihydrogen phosphate and Disodium hydrogen phosphate.

20. A process for the preparation of an aqueous Ifosfamide composition comprising bringing in intimate contact Ifosfamide, 2-hydroxypropyl-β-cyclodextrin, and water to form an aqueous Ifosfamide/2-hydroxyl-β-cyclodextrin solution.

21. The process of claim 20, wherein the Ifosfamide is present at a concentration of 1-200 mg/ml.

22. The process of claim 20, wherein the Ifosfamide is present at a concentration of 10-100 mg/ml.

23. The process of claim 20, wherein the Ifosfamide is present at a concentration of 40-50 mg/ml.

24. The process of claim 20, wherein the Ifosfamide is present at a concentration of 200-500 mg/ml.

25. The process of claim 20, wherein the Ifosfamide is present at a concentration of 500-1,000 mg/ml.

26. The process of claim 20, wherein the Ifosfamide is present at a concentration of greater than 1,000 mg/ml.

27. The process of claim 20, wherein the 2-hydroxypropyl-β-cyclodextrin has a molar substitution by hydroxy propyl groups of 0.5-1.2.

28. The process of claim 20, wherein the molar ratio of Ifosfamide to 2-hydroxypropyl-β-cyclodextrin is 100:0.1 - 1:300.

29. The process of claim 20, wherein the molar ratio of Ifosfamide to 2-hydroxypropyl-β-cyclodextrin is 100:0.25 - 1: 100

30. The process of claim 20, wherein the molar ratio of Ifosfamide to 2-hydroxypropyl-β-cyclodextrin is 100:1 - 1: 20

31. The process of claim 20, wherein the molar ratio of Ifosfamide to 2-hydroxypropyl-β-cyclodextrin is 100:3.3 - 1:2.5

32. The process of claim 20, further comprising adding one or more pharmaceutically acceptable buffers, tonicity agents, preservatives, chelating agents, antioxidants, or anti-crystallizing agents while bringing in intimate contact the Ifosfamide with the 2-hydroxylproplyl-β-cyclodextrin.

33. The process of claim 20, further comprising adding one or more pharmaceutically acceptable buffers, tonicity agents, preservatives, chelating agents, antioxidants, or anti-crystallizing agents to the Ifosfamide/2-hydroxylproplyl-β-cyclodextrin solution.

34. The process of claim 32, further comprising sterilization by filtering through a sterile 0.2 μm filter.

35. The process of claim 33, further comprising aseptically placing the solution into sterile containers followed by purging of air in the containers with an inert gas, followed by sealing the containers.

36. An aqueous Ifosfamide composition according to claim 1 wherein each ml of the composition comprises:

Ifosfamide: 500 mg; and

2-hydroxylpropyl-β-cyclodextrin: 400 mg.

37. An aqueous Ifosfamide composition according to claim 1 wherein each ml of the composition comprises:

Ifosfamide: 1000 mg; and

2-hydroxylpropyl-β-cyclodextrin: 50 mg.

38. An aqueous Ifosfamide composition according to claim 1 wherein each ml of the composition comprises:

Ifosfamide: 50 mg;

2-hydroxylpropyl-β-cyclodextrin: 100 mg;

Sodium dihydrogen phosphate: 0.3 mg; and

Disodium hydrogen phosphate: at 0.5 mg.